

Application No. 10/600,303  
Amendment dated May 17, 2006  
Reply to Office Action of February 17, 2006

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Docket No.: 61562(50530)

### **REMARKS**

Claims 1-19 are pending. Claims 9-19 are withdrawn. Applicants have cancelled withdrawn claims 18-19 without prejudice and added new claim 20. Applicants request entry and consideration of the following comments and amendments in response to the outstanding rejections. Support for these amendments appears throughout the specification and claims as originally filed. No new matter is introduced by these amendments. Applicants make these amendments in order to expedite prosecution of these claims. Applicants make such amendments without prejudice to pursuing the originally presented or cancelled subject matter in a later application claiming benefit of this application, and particularly without prejudice to determination of equivalents of the subject matter of this application or any later application claiming benefit of this application.

#### **Rejection under 35 U.S.C. §112, first paragraph**

Claims 1-8 are rejected as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make or use the invention. Applicants traverse. It is asserted in the Action that because no data is presented, "the claimed compounds *may well be inactive*"(emphasis added), and that "undue experimentation" would be required to practice the claimed invention. Applicants disagree.

Applicants have described throughout the specification and claims as filed how to make and use the compounds and methods thereof. This includes, at pages 41, line 6 to page 43, line 18, delineation of a variety of *in vitro* and *in vivo* methods (much, if not all, of which are substantially standard procedures known in the art) to measure activity of the instant compounds, as well as a myriad of examples as to how to make representative compounds.

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Under MPEP 2164.04, the burden is on the Examiner to establish a reasonable basis to question enablement. See, *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1161, 1167-68 (Fed. Cir. 1994). "In such a case, the examiner should specifically identify what information is missing and why one of ordinary skill in the art could not supply the information without undue experimentation." MPEP 2164.04. Further, "an extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "Time and difficulty of experiments are not determinative if they are merely routine." MPEP 2164.06.

Applicants submit that the disclosure of how to make, use and test the claimed compounds, as well as methodology to assay such compounds does not rise to the level of necessitating "undue experimentation" on the part of one of ordinary skill to practice the invention. Applicants submit that no support is provided in the Action to adequately establish a reasonable basis to question the enablement provided for the claimed invention such that there is a reason to doubt the objective truth of the statements in the specification as filed; and moreover, no support is provided in the Action that any such alleged missing information could not be supplied by one of ordinary skill in the art without undue experimentation. Applicants submit that delineation of assay protocols combined with the knowledge of one of ordinary skill in the art render such experiments merely routine. As such, Applicants submit that the rejection is unsupported and respectfully request that it be withdrawn.

### Objection

Claim 2 is objected to for grammatical reasons. Applicants have amended claim 2 to repair the grammar. Applicants respectfully request that the objection be withdrawn.

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Rejection under 35 U.S.C. §112, second paragraph

Claims 2-8 are rejected as allegedly being indefinite. Applicants traverse.

Claim 2 is rejected for the phrase "previously defined". Applicants have amended claims 2-6 as suggested in the Action to define W, X, Y and Z as in claim 1.

Claims 2-7 are rejected as lacking antecedent basis. Applicants have amended claim 1 to recite "compound".

Claim 7 is rejected for punctuation. Applicants have amended claim 7 as suggested in the Action to repair the punctuation.

Claim 8 is rejected as indefinite as to the objectives of the phrase "therapeutic efficacy". Applicants traverse. Applicants have amended claim 8 to recite "therapeutically effective against immune disorders". Support for this amendment appears at page 39, lines 27-29 of the specification.

On the basis of the foregoing, Applicants respectfully request withdrawal of the rejections.

Applicants also request rejoinder of method claims 9-17 pursuant to MPEP 821.04 as they are commensurate in scope with product claims 1-8 and 20.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is

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respectfully requested to pass this application to issue. Should any of the claims not be found to be in condition for allowance, the Examiner is requested to call Applicants' undersigned representative to discuss the application. Applicants thank the Examiner in advance for this courtesy.

The Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. (50530) 61562.

Dated: May 17, 2006

Respectfully submitted,

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